

### **REMARKS**

Reconsideration of this application is respectfully requested.

Claims 68-84 were previously pending. No claims have been amended, added or canceled by this paper. Accordingly, claims 68-84 are presented for further examination on the merits.

A couple of minor errors on pages 13 and 14 in the specification have been corrected.

#### **The First Rejection Under 35 U.S.C. §102(e)**

Claims 68-79 and 81-84 stand rejected under 35 U.S.C. §102(e) as being anticipated by Wong-Staal et al. (U.S. Patent No. 5,650,309). In the Office Action (pages 2-3), the Examiner stated:

This rejection is maintained for reasons of record in the previous Office Action (Paper #4) and for reasons outlined below.

Applicants traverse this rejection by asserting that the Wong-Staal et al. reference does not disclose nucleic acid constructs wherein the second viral nucleic acid or the second nucleic acid construct is structurally different from the first (i) viral nucleic acid or the first (ii) nucleic acid construct, or more than one packaging component for the second viral vector is different from said first viral vector packaging component or components (b), or both.

Applicants' arguments filed 12/18/98 have been considered but are not deemed persuasive. As noted in the previous Office Action, Wong-Staal et al. recites the generation of a recombinant vector (a first vector) comprising sequences from retrovirus and AAV genomes, wherein said first vector can produce a second vector which can be single or double stranded RNA or DNA and hence is structurally different from the first vector. With regard to the differences in packaging components, it is noted that packaging components comprising different surface or envelope components provided in the packaging cell can package the AAV portion of a chimeric AAV/HIV vector into AAV particles which have more than one packaging component different from the original HIV particle. Therefore, it must be assumed that Wong-Staal et al. teaches the invention as claimed.

The anticipation rejection is respectfully traversed.

In response, Applicants respectfully point out that there is a clear lack of identity of material elements between their claimed invention and Wong-Staal et al. In the case of the latter cited patent, one vector is simply used to make another vector in the host. In other words, Wong-Staal et al. transduce a host cell with a vector whose nucleic acid sequence is integrated into the host cell's chromosome. In contrast, Applicants' claimed invention requires a first vector which is capable of producing in a packaging cell a second vector. Furthermore, the packaging cell is capable of providing one or more packaging components for the second viral nucleic acid. These features of Applicants' invention are exquisitely shown in Figure 9 and are also exemplified in Example 8 (Propagation of AAV vectors from a Heterologous Vector Retrovirus inactivated for ppt function and containing Non-Native Vector Components derived from AAV) on page 55 in the specification. The requirements for a packaging cell which produces a second vector from the first vector and which also provides packaging components for a second viral nucleic acid are neither disclosed nor suggested in Wong-Staal et al.

In view of the foregoing remarks and the lack of material identity of elements, Applicants respectfully request reconsideration and withdrawal of the anticipation rejection based upon Wong-Staal et al.

**The Second Rejection Under 35 U.S.C. §102(b)**

Claims 68 and 70-74 stand rejected under 35 U.S.C. §102(b) for being anticipated by Salmons et al. ["Targeting of Retroviral Vectors for Gene Therapy," Human Gene Therapy 4:129-141(1993)]. In the Office Action (pages 3-4), the Examiner stated:

Applicants' traverse of this rejection is similar to the traverse of the above 35 USC 102(e) rejection of claims 68-79 and 81-84.

Salmons et al. teaches the claimed invention because the reference teaches a first and second vector wherein the two vectors differ in chemical structure (i.e. a DNA provirus vector vs. an RNA viral vector) wherein the second vector is capable of expressing an exogenous gene in a target cells and said vector contains a promoter, enhancer, termination sequences, etc. Therefore, Salmons et al. anticipates the claimed invention.

The anticipation rejection is respectfully traversed.

In response, Applicants would like to point out that Salmons' disclosure can be materially distinguished from their claimed invention in that Salmons et al. only discloses a packaging cell line which carries a gene for a first vector. By way of contrast, the present invention uses a packaging cell for producing a second vector from a first vector. In addition, the packaging cell of the present invention provides packaging components for the second viral nucleic acid, a material element altogether lacking in Salmons et al.

#### **Sequence Listing**

Applicants and their attorney acknowledge with appreciation the indication from the Examiner that the Sequence Listing from the parent application will be used to prepare a Sequence Listing for the instant application.

#### **Commonality of Ownership**

Applicants affirm that the subject matter of the various claims was commonly owned at the time their invention was made.

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Serial No. 09/046,840

Filed: March 24, 1998

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**The Rejection Under 35 U.S.C. §103(a)**

Claim 80 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Wong-Staal et al. (U.S. Patent No. 5,650,309), cited *supra.*, in view of Bank et al. (U.S. Patent No. 5,278,056). On pages 4-5 of the Office Action, the Examiner stated:

Applicants claim a packaging cell line (such as NIH 3T3) for propagating the vector of claim 68, wherein the first vector comprises a retrovirus and wherein the second vector comprises an adeno-associated virus.

Wong-Staal et al. is applied as in the above 35 USC 102(e) rejection of claims 68-79 and 81-84. Wong-Staal et al. does not recite the claimed packaging cell lines.

Bank et al. recites the use of the NIH 3T3 cell line as a packaging cell line for retroviral vectors.

The claimed subject matter is disclosed by Wong-Staal et al. with the exception of using the recited packaging cell lines recited in claim 80. The ordinary skilled artisan would have been motivated to use a well known packaging cell line (such as NIH 3T3) to package the claimed vectors since Bank et al.; teaches use of the NIH 3T3 cell line for packaging retroviral vectors. It would have been obvious for the ordinary skilled artisan to use a cell line such as NIH 3T3 because Bank et al. indicates that this cell line can be used to package retroviral vectors. Indeed, applicants themselves admit that the packaging cell line for the claimed vectors can be selected from a variety of packaging cell lines which are known in the art (See Specification, p. 28). Given the well known teachings of the cited references and the level of skill in the art at the time the invention was made, it must be considered that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

The obviousness rejection is respectfully traversed.

It is believed that even the combination of Bank et al. and Wong-Staal et al. is insufficient to reach Applicants' present invention. As stated above with respect to the first anticipation rejection, Wong-Staal et al. does not disclose or even suggest that a second vector could or even should be produced from a first vector in a packaging cell that also provides packaging components for the second viral

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nucleic acid. Adding Bank's patent to Wong-Staal's does not cure this deficiency. Accordingly, the present invention would not have been obvious to a person of ordinary skill in the art at the time it was made from a combined reading of Bank's and Wong-Staal's patent disclosures.

Reconsideration and withdrawal of the obviousness rejection is, therefore, respectfully requested.

\* \* \* \* \*

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Filed: March 24, 1998

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### **SUMMARY AND CONCLUSIONS**

Claims 68-84 are presented for further examination, no claims having been amended, added or canceled.

This paper is accompanying a Petition To Revive An Unintentionally Abandoned Application Under 37 C.F.R. §1.137(b) and authorization for the small entity fee therefor. No other fee or fees are believed due in connection with this filing. In the event that any other fee or fees are due, however, the Patent and Trademark Office is authorized to charge the amount of any such fee(s) to Deposit Account No. 05-1135, and to credit any overpayment thereto.

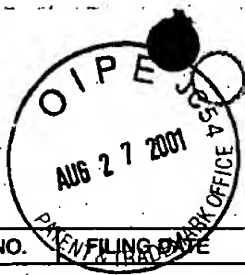
In view of the above discussion of the issues, Applicants respectfully request reconsideration and withdrawal of all grounds of rejection. Should it be deemed helpful or necessary, the Examiner is respectfully invited to telephone the undersigned at (212) 583-0100 to discuss the subject application.

Respectfully submitted,



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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/046,840 03/24/98 LIU

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EXAMINER

HM12/0117

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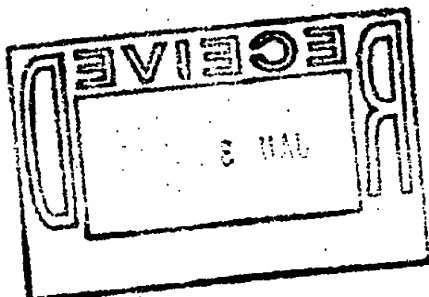
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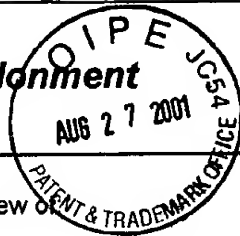
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# Notice of Abandonment



Application No.

09/046,840

Applicant(s)

Liu et al.

Examiner

David Guzo

Group Art Unit

1636



This application is abandoned in view of

☒ applicant's failure to timely file a proper response to the Office letter mailed on May 26, 2000.

☐ A response (with a Certificate of Mailing or Transmission of \_\_\_\_\_) was received on \_\_\_\_\_, which is after the expiration of the period for response (including a total extension of time of \_\_\_\_\_ month(s)) which expired on \_\_\_\_\_.

☐ A proposed response was received on \_\_\_\_\_, but it does not constitute a proper response to the final rejection.

(A proper response to a final rejection consists only of: a timely filed amendment which places the application in condition for allowance; a Notice of Appeal; or the filing of a continuing application under 37 CFR 1.62 (FWC)).

☒ No response has been received.

☐ applicant's failure to timely pay the required issue fee within the statutory period of three months from the mailing date of the Notice of Allowance.

☐ The issue fee (with a Certificate of Mailing or Transmission of \_\_\_\_\_) was received on \_\_\_\_\_.

☐ The submitted issue fee of \$ \_\_\_\_\_ is insufficient. The issue fee required by 37 CFR 1.18 is \$ \_\_\_\_\_.

☐ The issue fee has not been received.

☐ applicant's failure to timely file new formal drawings as required in the Notice of Allowability.

☐ Proposed new formal drawings (with a Certificate of Mailing or Transmission of \_\_\_\_\_) were received on \_\_\_\_\_.

☐ The proposed new formal drawings filed \_\_\_\_\_ are not acceptable.

☐ No proposed new formal drawings have been received.

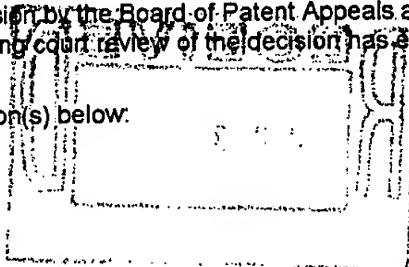
☐ the express abandonment under 37 CFR 1.62(g) in favor of the FWC application filed on \_\_\_\_\_.

☐ the letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

☐ the letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

☐ the decision by the Board of Patent Appeals and Interferences rendered on \_\_\_\_\_ and because the period for seeking court review of the decision has expired and there are no allowed claims.

☐ the reason(s) below:

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DEPUTY A/C PATENTSDAVID GUZO  
PRIMARY EXAMINER